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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/300,482 | 04/28/1999 | NORDINE CHEIKH | 04983.0031.U | 4511 |

28381 7590 01/02/2003

ARNOLD & PORTER
IP DOCKETING DEPARTMENT; RM 1126(b)
555 12TH STREET, N.W.
WASHINGTON, DC 20004-1206

| EXAMINER | |
|---|---|
| MORAN, MARJORIE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | 22 |

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/300,482 | CHEIKH ET AL. | |
| | Examiner | Art Unit | |
| | Marjorie A. Moran | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,10-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,10-13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and rejections not repeated below are hereby withdrawn. Claims 1-2, 10-13, and 15-23 are pending.

***Priority***

Applicant is reminded that priority is granted to the filing of the Provisional application (filed 4/29/1998) for only claims 12, 16, and 21, as set forth in the office action of 7/17/02. As previously set forth, applicant admitted on page 1 of the response filed 9/27/01 that SEQ ID NO's 4, 14, 27, 298, 311, 356, and 569 are not supported by the Provisional, therefore claims 1-2, 11, 13-15 and 17-20, and new claims 22-23, which recite these sequences, are accorded priority only to the filing date of the instant application, of 4/28/1999. Applicant is advised, therefore, that references reciting dates of publication or public availability prior to 4/28/99 are prior art under 35 USC 102 for claims 1-2, 11, 13,15, 17-20, and 22-23.

***35 U.S.C. 112, Written Description Rejection***

Claims 1-2, 10-13, and 15-21 are rejected, as previously set forth in the office actions of 12/20/00,12/4/01, and 7/17/02, and new claims 22-23 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 10/17/02 have been fully considered but they are not persuasive. Applicant's arguments are addressed below.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description

provisions of 35 USC 112, first paragraph. However, claims 1, 2, and 22 recite open claim language (comprising) and claims 1 and 10 are specifically directed to encompass sequences that hybridize to the claimed SEQ ID NO's. As the sequences recited in the claims are apparently fragments which do not appear to comprise ORF's or actually encode any known proteins, a nucleic acid "comprising" the fragments encompasses much larger sequences which may encode entirely different proteins from those recited, encompasses genomic sequences which may also comprise introns, noncoding regions, etc. In particular, a genomic sequence significantly longer in length than a claimed fragment may still hybridize to a recited sequence under the claimed conditions as introns, etc. may "bubble" out where mismatches occur but still allow for sufficient length of the genomic sequence to anneal under the claimed conditions. The specification sets forth a list of possible variations for the inventive sequences, as argued by applicant, but does not actually describe, by sequence or structure, any of the variations, nor does the specification disclose any longer sequences (e.g. genomic) which may comprise the claimed sequences. For these reasons, the examiner maintains that the specification provides insufficient written description to support the genus encompassed by the claim.

With regard to sequence similarity to nucleic acids encoding known proteins/enzymes, it is noted that, as previously set forth, the specification does identify enzymes which are known in the prior art and have some sequence similarity to the claimed sequences. However, and also as previously set forth, the sequences recited have not been shown to encode an entire enzyme, nor has any particular ORF been identified for the claimed sequences. Applicant acknowledges that BAKER et al. (Science (10/5/2001), vol. 294, pages 93-96) is directed to controversy in the art over prediction of function based on homology alone, but argues that the examiner does not "take into consideration Applicant's disclosure." On the contrary, the previous office action stated that Table A of the specification discloses sequence similarity information (e.g. % identity) between peptides putatively encoded by the claimed sequences and sequences which encode known enzymes, but that no comparison of binding regions, conserved regions, catalytic regions, etc. is shown to support that the peptides putatively encoded by the claimed SEQ ID NO's would be expected to actually exhibit ANY enzyme activity. For example, BAKER teaches that structural (de novo) models are more accurate at predicting functional homologies between proteins, especially where sequence comparison fails (p. 94). Applicants argue that a structure is described; i.e. the nucleic acid sequence. It is

noted that while a nucleic acid sequence is a chemical structure, a nucleic acid "structure" is not the same as a peptide or protein structure, and is not necessarily predictive of a protein structure putatively encoded thereby. Given the acknowledged controversy in the art over whether sequence similarity alone can be used to accurately predict function, and the lack of teaching in the specification for whether any of the claimed nucleic acids actually encodes any protein, specifically one of the recited enzymes, and absent factual evidence to the contrary, one skilled in the art would reasonably doubt that sequence similarity alone is sufficient to predict whether the biological and enzymatic activity of the claimed subject matter is the same as that of the prior art. The specification fails to describe ANY nucleic acid actually encoding one or more of the claimed enzymes, therefore the rejection is maintained.

With the exception of sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

Claims 1 and 22 recite a "substantially purified nucleic acid" which encodes a "maize or soybean phosphogluconate pathway enzyme" wherein the nucleic acid is a specific SEQ ID NO: or hybridizes to specific SEQ ID NO's. The specification fails to describe any "substantially purified nucleic acid sequence" which is known to encode a maize or soybean phosphogluconate pathway enzyme. Once purified, nucleic acid and peptide sequences do not carry information with regard to their origin. An enzyme expressed from a nucleic acid will display activity, under appropriate conditions, no matter what system, cell line, clone, etc. it is expressed from/in. A purified sequence (comprising a complete ORF) may be cloned into another plant/cell line and a protein expressed; is the protein still a "maize or soybean" enzyme? In addition, it is noted that sequences which hybridize to one of the claimed nucleic acids under the conditions recited, and encode one of the recited enzymes, but are NOT sequences purified from maize or soybean are known in the art (see e.g. the sequence taught by MARTIN et al., set forth in the previous office action). As the specification fails to describe a "substantially purified nucleic acid" which encodes a "maize or soybean" enzyme, the rejection of claim 1 for lack of written description is maintained and claim 22 is newly rejected.

***Claim Rejections - 35 USC § 102***

Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by UCHIMIYA (NCBI accession number D43256, 5/4/1998), as supported by MEINKOTH et al. (Analytical Biochem. (1984), vol. 138, pp. 267-284) as supported by MEINKOTH et al. (Analytical Biochem. (1984), vol. 138, pp. 267-284).

Applicant's arguments with respect to claim 10 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments are addressed below.

UCHIMIYA discloses a cDNA/mRNA sequence which is 74.6% identical/complementary to SEQ ID NO: 619.

Using the equation taught by MEINKOTH (p. 269; Tm=81.5°C + 16.6 log M + (0.41 (%G+C) -500/n; applicant uses no formamide, so that part of MEINKOTH's equation would be "zero" and is not included herein) and subtracting 1°C for every 1% of mismatched base pairs (p. 270), the melting point of a duplex between SEQ ID NO: 619 and UCHIMIYA's sequence would be 76.5°C at 0.33M salt, therefore UCHIMIYA's sequence would inherently hybridize to SEQ ID NO: 619 or its complement under the recited conditions. In response to arguments regarding "burden of proof" and evidence of hybridization, it is noted that in In re Best, Bolton, and Shaw (195 USPQ at 431), it was decided that the "burden of proof is on applicant where rejection is based on inherency under 35 USC 102...and the Patent and Trademark's inability to...obtain and compare prior art products evidences fairness of this rejection". As previously set forth, the Office does not have the facilities to carry out hybridization experiments. The examiner has provided mathematically derived evidence that UCHIMIYA's sequence would be expected to hybridize under the claimed conditions. Applicant has not provided evidence to the contrary, therefore the examiner maintains that UCHIMIYA's sequence inherently meets the

claimed limitations, and maintains the rejection. In response to the argument that UCHIMIYA is not a proper reference under 35 USC 102, applicant is reminded that claims reciting any of SEQ ID NO's 4, 27, 298, 311, 356, or 569 are granted priority only to the filing date of the instant application, of 4/28/99. It is noted that claim 10 recites all of these SEQ ID NO's. The date that UCHIMIYA's sequence was "first seen" on NCBA was 5/4/1998, which is before the priority date granted to claim 10, therefore the examiner maintains that the rejection is proper.

Claims 1 and 10 are rejected under 35 U.S.C. 102 (a) and (b) as being anticipated by KATSURADA (NCBI accession number AB007907) as supported by MEINKOTH et al. (Analytical Biochem. (1984), vol. 138, pp. 267-284).

Applicant's arguments with respect to claims 1 and 10 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments are addressed below.

KATSURADA teaches a cDNA/mRNA which encodes a soybean 6-phosphogluconate dehydrogenase and is 59.5% identical to SEQ ID NO: 27.

Using the equation taught by MEINKOTH (p. 269; Tm=81.5°C + 16.6 log M + (0.41 (%G+C) -500/n) and subtracting 1°C for every 1% of mismatched base pairs, as set forth above, the melting point of a duplex between SEQ ID NO: 27 and KATSURADA's sequence would be 65.9°C at 0.33M salt, therefore KATSURADA's sequence would inherently hybridize to SEQ ID NO: 27 under the recited conditions. In response to arguments regarding "burden of proof" and evidence of hybridization, it is noted that in In re Best, Bolton, and Shaw (195 USPQ at 431), it was decided that the "burden of proof is on applicant where rejection is based on inherency under 35 USC 102...and the Patent and Trademark's inability to...obtain and compare prior art products evidences fairness of this rejection". As previously set forth, the Office does not have the facilities to carry out hybridization experiments. The examiner has provided mathematically

derived evidence that KATSURADA's sequence would be expected to hybridize under the claimed conditions. Applicant has not provided evidence to the contrary, therefore the examiner maintains that KATSURADA's sequence inherently meets all of the claimed limitations, and maintains the rejection.

Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by WALBOT (NCBI accession number AI586588, first seen 4/7/1999) as supported by MEINKOTH et al. (Analytical Biochem. (1984), vol. 138, pp. 267-284).

WALBOT teaches a cDNA/mRNA which is 71.0% identical to SEQ ID NO: 356.

Using the equation taught by MEINKOTH (p. 269; Tm=81.5°C + 16.6 log M + (0.41 (%G+C) -500/n) and subtracting 1°C for every 1% of mismatched base pairs, as set forth above, the melting point of a duplex between SEQ ID NO: 356 and WALBOT's sequence would be 73.9°C at 0.33M salt, therefore WALBOT's sequence would inherently hybridize to SEQ ID NO: 356 under the recited conditions. It is noted that in In re Best, Bolton, and Shaw (195 USPQ at 431), it was decided that the "burden of proof is on applicant where rejection is based on inherency under 35 USC 102...and the Patent and Trademark's inability to...obtain and compare prior art products evidences fairness of this rejection". As previously set forth, the Office does not have the facilities to carry out hybridization experiments. The examiner has provided mathematically derived evidence that WALBOT's sequence would be expected to hybridize to SEQ ID NO: 356 under the claimed conditions, therefore in the absence of evidence to the contrary, WALBOT's sequence inherently meets all of the claimed limitations, and claim 10 is anticipated.

Claims 1 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by BOUVIER et al. (NCBI accession number Y15781, first seen on NCBI 9/9/1998) as supported by MEINKOTH et al. (Analytical Biochem. (1984), vol. 138, pp. 267-284).

BOUVIER teaches a cDNA/mRNA which encodes a transketolase and is 48.8% identical to SEQ ID NO: 356.

Using the equation taught by MEINKOTH (p. 269; Tm=81.5°C + 16.6 log M + (0.41 (%G+C) -500/n) and subtracting 1°C for every 1% of mismatched base pairs, as set forth above, the melting point of a duplex between SEQ ID NO: 356 and BOUVIER's sequence would be 55.4°C at 0.33M salt, therefore BOUVIER's sequence would inherently hybridize to SEQ ID NO: 356 under the recited conditions. It is noted that in In re Best, Bolton, and Shaw (195 USPQ at 431), it was decided that the "burden of proof is on applicant where rejection is based on inherency under 35 USC 102...and the Patent and Trademark's inability to...obtain and compare prior art products evidences fairness of this rejection". As previously set forth, the Office does not have the facilities to carry out hybridization experiments. The examiner has provided mathematically derived evidence that BOUVIER's sequence would be expected to hybridize to SEQ ID NO: 356 under the claimed conditions. In the absence of evidence to the contrary, BOUVIER's sequence inherently meets all of the claimed limitations, and therefore anticipates claims 1 and 10.

***Conclusion***

Claims 1-2, 10-13, and 15-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran

December 28, 2002